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Background: Transcatheter aortic valve implantation (TAVI in patients with large aortic annuli (>26mm) can be challenging and may be associated with suboptimal results, particularly as regards to post-procedural aortic regurgitation (AR). Recently, Direct Flow Medical (DFM) introduced the 29mm version of their fully repositionable and retrievable valve to treat aortic annuli measuring 26 to 28.5mm.
Methods: All consecutive patients successfully implanted with a 29mm DFM valve between December 2013 and May 2014 were retrospectively analyzed in this multi-center European study. Endpoints were defined according to VARC-2 criteria peri-procedurally and at 30 days.
Results: A total of 36 high- and extreme-risk patients with severe aortic stenosis were implanted with a 29mmDFM valve. The mean age of patients was 82±4.6 years and 90% were males. The average annular diameter and perimeter were 27.4±1.2mm and 86.8±3.4mm, respectively. The 29mm DFM was oversized in relation to the native annulus by 4.9%±3.9% by diameter and 5.0%±4.0% by perimeter. Implantation of the 29mm DFM resulted in a reduction of mean transaortic gradient from 41.9±15.8mmHg to 6.1±5.1mmHg. Device success was achieved in 97% of patients. Implantation of a DFM valve was associated with none or trivial AR in 81%, mild AR in 17%, and moderate AR in 1 (2%) patient. There were no coronary occlusions, device embolizations, annular rupture or intraprocedural deaths. Complete 30-day outcomes will be available and presented at the meeting.
Conclusions: The Direct Flow Medical Transcatheter Aortic Valve System was associated with excellent peri-procedural outcomes and virtually eliminated AR in patients with aortic stenosis and a large annulus.

TCT-711

PROCEDURAL AND CLINICAL OUTCOMES OF SUBCLAVIAN VERSUS TRANSAORTIC APPROACH FOR TRANSCATHETER AORTIC VALVE REPLACEMENT WITH SELF-EXPANDABLE COREVALVE: AN ITALIAN MULTICENTER EXPERIENCE

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Background: Trans-femoral approach represents the first choice of vascular access for transcatheter aortic valve replacement (TAVR). When not feasible, alternative approaches such as subclavian or direct ascending aorta (transaortic rout) are used for self-expandable CoreValve implantation. Aim of this work was to compare the safety of TAVR with self-expandable valve through these alternative vascular approaches.
Methods: All consecutive patients underwent TAVR with self-expandable CoreValve prosthesis treated through alternative approach in 4 high volume Italian Centre. Devices success and combined safety endpoint according to VARC-2 criteria were evaluated.
Results: Among 1049 patients undergoing CoreValve implantation between September 2007 and February 2014, 242 (23%) have been treated through alternative access: subclavian (147/242, 61%) and transaortic (95/242, 39%) route because of peripheral artery disease. Demographic features were quite similar in both groups except for a higher clinical risk profile [median STS: 10% (IQR 6-14%) vs 6% (IQR 4-12%), p< 0.001] and previous CABG (20% vs 10%, p=0.021) in transaortic group compared to subclavian one. Device success was similar in two groups (87% vs 80%, respectively; p=0.164). The subclavian group showed higher rate of fluoro time [22 min (IQR 16-28) vs 17 min (IQR 13-20), p=0.05] and contrast used (192±81 ml vs 148±63 ml, p< 0.001). The transaortic group showed a higher incidence of combined safety end point (27% vs 16%, p=0.04) mostly driven by a higher rate of acute kidney injury/stage 2-3 (10% vs 2%, p=0.01) as well as the length of hospital stay [10 days (IQR 8-14) vs 8 days (IQR 7-12), p< 0.001]. Compared to subclavian group, the transaortic had a similar cumulative incidence of survival rate at 30-day (94.6% vs 90%, respectively; p=0.21).
Conclusions: Compared to subclavian, the transaortic group had higher clinical risk profile with a higher incidence of combined safety endpoint mostly due to acute kidney injury/stage 2-3. However, no differences were observed in the device success and survival rate at 30-day.

TCT-712

Better Outcomes with Sapien 3 vsSapien XT balloon-expandable prosthesis in patients undergoing transfemoral aortic valve replacement

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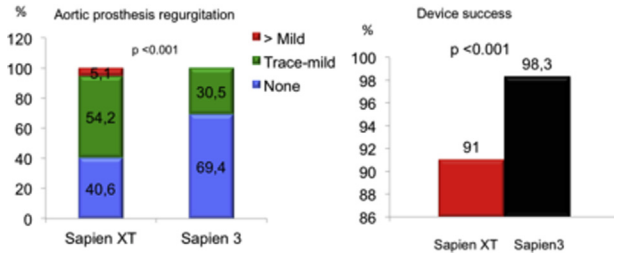
Background: Residual regurgitation remains a limitation of the early generations of aortic prostheses and is associated with increased mortality. Thus newer devices have been developed to address this complication. The aim of this study was to assess performance of second generation Sapien XT (SXT)vs. the third generation Sapien 3(S3)in patients with severe aortic stenosis (AS) undergoing transfemoral aortic valve implantation (TAVI).
Methods: We analyzed a total of 413 patients undergoing implantation of balloon-expandable Sapien prosthesis in our institution treated whether with SXT (n=354) or the S3 (n=59).Outcomes were defined according to the standardized Valve Academic Research Consortium-2 criteria (VARC-2).
Results: Mean age of the TAVI patients was 80.7±7.6 years, 55% of them were women and median prosthesis size was 26mm. No differences regarding the baseline characteristic were observed among both groups. Balloon post-dilatation was performed more frequently after implantation of the SXT than S3 prosthesis (30.8% vs. 8.4% p< 0.01). The incidence of relevant prosthesis regurgitation directly after procedure and of device failure was significantly higher among SXT group (Figure).



Conclusions: The third generation balloon-expandable Sapien 3 is safer and more feasible compared to the second generation Sapien XT valve system.

TCT-713

The double-edged sword of antiplatelet treatment following transcatheter aortic valve implantation – a collaborative patient level pooled analysis

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Background: Evidence is lacking to support decision making on antiplatelet therapy following transcatheter aortic valve implantation (TAVI).
Methods: All available studies comparing single with dual antiplatelet treatment (DAPT) following TAVI were included in a collaborative patient level pooled analysis. The principal investigator for each trial was approached. Primary endpoint was defined as the composite of major adverse cerebrovascular and cardiovascular events (MACCE) at one month, including all-cause mortality, acute coronary syndrome (ACS), stroke, life threatening or major bleeding.